

outstanding Office Action.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejects Claims 1-7 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. According to the Examiner, claims cannot begin with the term “use.” Because Applicants have canceled Claims 2 and 3, their rejection is now moot. Applicants have amended Claims 1 and 4-7 and, therefore, respectfully request that the rejection of these claims be withdrawn.

Rejection under 35 U.S.C. §103(a)

The Examiner rejects Claims 1-14 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,792,754 to Green et al. (“Green”). Applicants have canceled Claims 2 and 3 and have amended Claims 1 and 4-8. Applicants respectfully traverse the rejection of the remaining claims and submit that those claims are patentable over the prior art.

U.S. Patent No. 5,792,754 to Green teaches a nutritional composition containing fibers. The composition may be used to maintain gut function and to clear toxins by providing stool bulk and substrate for intestinal flora (col. 1, lines 12-15). Green, therefore, discloses a nutritional composition that may be used only to treat local infections, *i.e.*, infections that affect only a restricted part of the body. See Webster’s Medical Desk Dictionary, p. 393 (1986) (courtesy copy enclosed).

Unlike the invention disclosed by Green, the present invention relates to a method of preventing, inhibiting and treating systemic infections caused by pathogenic bacteria in humans and other vertebrates, as well as to a method of manufacturing a composition for use in the method

of preventing, inhibiting and treating systemic infections caused by pathogenic bacteria. Systemic infections are those that affect the body generally. See Webster's Medical Desk Dictionary, p. 700 (courtesy copy enclosed). Green is completely silent about the prevention and/or treatment of systemic infections, as well as a method of accomplishing the same. The present invention, therefore, is clearly different from that of Green in which a nutritional composition containing fibers may be used to treat local infections in the digestive tract, *i.e.*, by clearing toxic compounds from the intestines by providing stool bulk and substrate for intestinal flora (col. 1, lines 12-15).

The Examiner also asserts that the average degree of polymerization ("av. DP") of the dietary fibers fails to impart a patentable characteristic to the present invention. Applicants respectfully disagree with this assertion. It is clear from the results of Examples 1 and 2 of the present invention, as displayed in Figures 1 and 2, that the av. DP of the inulin products, *i.e.*, RAFTILOSE® P95 and RAFTILINE® HP, has an effect on the prevention and/or inhibition of systemic infections. Indeed, the inulin product with the higher av. DP, *i.e.*, RAFTILINE® HP, shows more pronounced beneficial effects, particularly a significantly lower mortality rate, compared to the inulin product with the lower av. DP.

New Claims 15-22

Applicants have added herein new Claims 15-22. These new claims all relate either to the prevention, inhibition and/or treatment of systemic infections in humans or vertebrates comprising the administration to a human or vertebrate suffering from such infection of a composition containing an affective amount of a dietary fiber or a mixture of dietary fibers or to a method of manufacturing a composition for preventing, inhibiting and/or treating such a systemic infection. Applicants respectfully submit that new Claims 15-22 are patentable over the prior art for the reasons discussed above with regard to the outstanding rejection of Claims 1 and 4-14 under 35

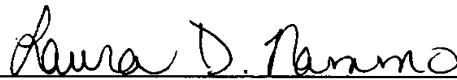
U.S.C. §103(a).

Conclusion

Applicants respectfully submit that the application is now in condition for allowance and respectfully request the Examiner take action indicating such.

Respectfully submitted,

PIPER MARBURY RUDNICK & WOLFE LLP

A handwritten signature in cursive script, appearing to read "Steven B. Kelber", is written over a horizontal line.

Steven B. Kelber

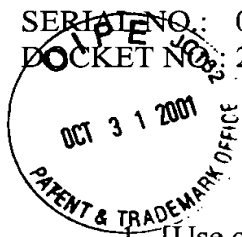
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MARKED-UP COPY OF AMENDED CLAIMS

1. [Use of a dietary fiber or mixture of dietary fibers for manufacture of] A method of manufacturing a composition for prevention, inhibition and/or treatment of systemic infections in humans and in vertebrates caused by pathogenic bacteria, comprising combining a dietary fiber or a mixture of dietary fibers with one or more pharmaceutically acceptable excipients to form the composition, wherein the composition is in conventional galenic form suitable for oral or rectal administration or for tube feeding.

4. [Use] The method according to Claim 1, wherein the dietary fiber is selected from the group consisting of lignin, cellulose, hemicellulose, pectin, gums, arabic gum, carrageenan, waxes, resistant oligosaccharides, oligofructose, resistant polysaccharides, resistant starch and fructan.

5. [Use] The method according to Claim 4, wherein the fiber is a fructan selected from the group consisting of levan, inulin and oligofructose.

6. [Use] The method according to Claim 5, wherein the fiber is chicory inulin with an average degree of polymerization (\overline{DP}) of at least 20.

7. [Use] The method according to Claim 6, wherein the fiber is chicory inulin with an average degree of polymerization (\overline{DP}) of at least 25.

8. [Method] A method for the prevention[, inhibition and/or treatment] of systemic infections in humans or vertebrates caused by pathogenic bacteria comprising administering to said humans or vertebrates a composition containing an effective amount of a dietary fiber or a mixture of dietary fibers.